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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,320	05/14/2001	Robert Bayer	19957-014110	1113

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/17/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/855,320	BAYER, ROBERT	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 22-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 31-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-65 are currently pending and are present for examination. Claims 1-21 and 31-65 are now under consideration. Claims 22-30 remain withdrawn from consideration as being drawn to non-elected invention.

Applicants' amendments and arguments filed on 6-29-03, paper No.10, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, 31-65 are rejected under 35 U.S.C. 112, first paragraph, as containing ~~subject matter which was not described in the specification in such a way as to reasonably~~ convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-21 and 31-65 are directed to a method of fucosylation using polypeptide with fucosyltransferase activity. Claims 1-21 and 31-65 are rejected under this section of 35 USC 112 because the claims are directed to a method of use of a genus of polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue that have not been disclosed in the specification. No description has been provided of the polypeptide sequences encompassed by the claim. No information, beyond the characterization of the polypeptides as fucosyltransferases or fucosyltransferases lacking

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membrane anchor domain, has been provided by applicants which would indicate that they had possession of the claimed genus of polypeptides. The specification does not contain any disclosure of the structure of all the polypeptide sequences, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structures. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21, 31-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seed et al. (WO 96/40881, 12-19-1996), Paulson et al. (WO 98/31826, 7-23-1998) and Taylor et al. (US 2003/0166212 A1, 9-4-2003). Claims 1-6, 8-21, 31-38, 40-65 of the instant application are drawn to a method of fucosylation of a glycopeptide comprising an acceptor moiety comprising contacting the glycopeptide with a reaction mixture containing fucose donor moiety and a

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fucosyltransferase under appropriate conditions to transfer fucose from the donor to acceptor such that the glycopeptide has a substantially uniform fucosylation pattern, wherein the fucosyltransferase lacks a membrane anchoring domain and is recombinantly produced, wherein 80% of the acceptor moieties are fucosylated, wherein the glycopeptide is a full length peptide, wherein the glycopeptide is an enzyme, cytokine etc. wherein the glycopeptide is on a cell, wherein the donor is a GDP-fucose.

Seed et al. teach an identical method of fucosylating a polypeptide (which when considered broadly would encompass glycopeptides as well) using a FucT-III fucosyltransferase enzyme produced recombinantly. The reference also provides sources for other fucosyltransferases such as FucT-IV and FucT-VII (see page 2). The reference does not explicitly report that 80% of the acceptor moieties are fucosylated. At the same time the reference does not also say that less than 80% of the moieties were fucosylated. Therefore, Examiner takes the position that this information is inherent in the reference and that 80% or more of the moieties were fucosylated.

(Furthermore, since the Office does not have the facilities for examining and comparing applicants' method with the method of the prior art reference, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594). The reference also does not teach the fucosylation of a glycopeptide or glycosylating the fucosylated glycopeptide with a glycosyl moiety other than a fucose unit.

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Taylor et al. teach a method of making a bacterial fucosyltransferase lacking membrane anchor domains. The reference actually teaches the production of such enzymes from *Helicobacter pylori*, the well known pathogen known to cause gastric disorders. The reference provides a host cell comprising a vector encoding the soluble enzyme.

Paulson et al. teaches methods for *in vitro* sialylation of recombinant glycoproteins. The reference essentially teaches a method of glycosylation involving an enzyme other than a fucosyltransferase.

Combining the teachings of the above three references, along with those commonly known regarding affinity chromatography etc. it would have been obvious to those skilled in the art, to alter the method of fucosylation of a polypeptide by Seed et al. by making and using a soluble recombinant fucosyltransferase such as FucT-IV, FucT-VI or FucT-VII lacking the membrane anchor domain or the retention signal, including enzymes isolated from bacteria using the method of Taylor et al. and use such enzymes to fucosylate a glycopeptide --either with a single enzyme or with more than one of the above enzymes either by using them simultaneously or sequentially--, that is already glycosylated (sialylated) as taught by Paulson(b) et al. One of ordinary skill in the art would be motivated to do so as Seed et al. teach that fucosylated proteins produce therapeutics useful for treatment of diseases such as adverse immune reaction. One of ordinary skill in the art would have a reasonable expectation of success since Seed et al. teach almost an identical system but with enzymes which may not lack membrane anchor domain which deficiency is overcome by the reference of Taylor et al. which teaches a bacterial fucosyltransferase and also method of making transmembrane anchor lacking enzyme.

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Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

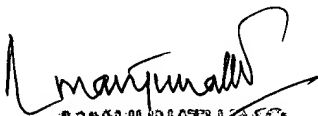
Conclusion

None of the claims are allowable. The indication of some claims as allowable has been withdrawn by the Examiner in view of the finding of prior art documents. Any inconvenience to the applicant is regretted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.


MANJUNATH N. RAO
PATENT EXAMINER
Manjunath N. Rao
November 12, 2003